

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/252,828	DONG ET AL.	
	Examiner	<b>Art Unit</b>	
	Suzanne M. Mayer, Ph.D.	1653	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address--*

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to a telephone call with Mr. Henry Wixon on April 14, 2005.
2.  The allowed claim(s) is/are 69-77.
3.  The drawings filed on 03 October 2003 are accepted by the Examiner.
4.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All    b)  Some\*    c)  None    of the:
    1.  Certified copies of the priority documents have been received.
    2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6.  CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a)  including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1)  hereto or 2)  to Paper No./Mail Date \_\_\_\_\_.
  - (b)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
7.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

#### Attachment(s)

1.  Notice of References Cited (PTO-892)
2.  Notice of Draftsperson's Patent Drawing Review (PTO-948)
3.  Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date 11-13-03 & 4-1-03
4.  Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5.  Notice of Informal Patent Application (PTO-152)
6.  Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_.
7.  Examiner's Amendment/Comment
8.  Examiner's Statement of Reasons for Allowance
9.  Other \_\_\_\_\_.

**EXAMINER'S AMENDMENT**

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Dr. Belinda Lew on April 7, 2005 and an additional confirmation was given by Mr. Henry Wixon on April 14, 2005.

The application has been amended as follows:

Claim 69: A recombinantly produced polypeptide expressed by a human ovarian cell line, consisting essentially of the amino acid sequence of SEQ ID No: 2, wherein said polypeptide binds human spermatozoa.

Claim 70: A recombinantly produced glycopolypeptide expressed by a human ovarian cell line, consisting essentially of the amino acid sequence of SEQ ID No: 2.

Claim 71: A recombinantly produced polypeptide expressed by a human ovarian cell line, consisting essentially of the amino acid sequence of SEQ ID No: 2, or a conservatively substituted amino acid sequence thereof, said conservative substitutions being at least one of the amino acid residue numbers; 3, 8, 13, 16, 17, 19, 21, 22, 23, 25, 27, 28, 30, 32, 33, 34, 35, 38 and 39 according to SEQ ID No: 2, wherein said polypeptide binds human spermatozoa at least ten times as strong as an equivalent molar amount of mouse ZP3.

Claim 72: A recombinantly produced glycopolypeptide expressed by a human ovarian cell line, consisting essentially of the amino acid sequence of SEQ ID No: 2, or a conservatively substituted amino acid sequence thereof, said conservative substitutions being at least one of the amino acid residue numbers; 3, 8, 13, 16, 17, 19, 21, 22, 23, 25, 27, 28, 30, 32, 33, 34, 35, 38 and 39 according to SEQ ID No: 2, wherein said polypeptide binds human spermatozoa at least ten times as strong as an equivalent molar amount of mouse ZP3.

Claim 73: A recombinantly produced polypeptide according to claim 71, wherein the conserved amino acid substitutions at the following positions of SEQ ID No: 2 are as follows:

- 3 is selected from the group consisting of Phe and Tyr;
- 13 is selected from the group consisting of Gln and Asp;
- 16 is selected from the group consisting of Asn and Gln;
- 19 is selected from the group consisting of Asp, Asn, Glu, Gln, Ile, Pro, Phe and Cys;
- 21 is selected from the group consisting of Gly, Ala and Ile;
- 22 is selected from the group consisting of Thr and Ser;
- 25 is selected from the group consisting of His and Lys;
- 27 is selected from the group consisting of Arg and Lys;
- 28 is selected from the group consisting of Arg and Lys;
- 30 is selected from the group consisting of Pro and Met;
- 32 is selected from the group consisting of Val, Ile and Met;

34 is selected from the group consisting of Ser and Thr;  
35 is selected from the group consisting of Gln and Asn; and  
38 is selected from the group consisting of Arg and Lys.

Claim 74: A recombinantly produced glycopolypeptide according to claim 72, wherein the conserved amino acid substitutions at the following positions of SEQ ID No: 2 are as follows:

3 is selected from the group consisting of Phe and Tyr;  
13 is selected from the group consisting of Gln and Asp;  
16 is selected from the group consisting of Asn and Gln;  
19 is selected from the group consisting of Asp, Asn, Glu, Gln, Ile, Pro, Phe and Cys;  
21 is selected from the group consisting of Gly, Ala and Ile;  
22 is selected from the group consisting of Thr and Ser;  
25 is selected from the group consisting of His and Lys;  
27 is selected from the group consisting of Arg and Lys;  
28 is selected from the group consisting of Arg and Lys;  
30 is selected from the group consisting of Pro and Met;  
32 is selected from the group consisting of Val, Ile and Met;  
34 is selected from the group consisting of Ser and Thr;  
35 is selected from the group consisting of Gln and Asn; and  
38 is selected from the group consisting of Arg and Lys.

Claim 75: A glycosolated recombinant human zona pellucida protein 3 expressed by a human ovarian cell line having sperm-binding and acrosome reaction inducing activity, consisting of SEQ ID No: 2.

Claim 76: The protein of claim 75, wherein the ovarian cell line is selected from the group consisting of PA-1, EB<sub>2</sub>, CaoV-3, OVCAR-3, SKOV-3 and SW 626.

Claim 77: The protein of claim 75, wherein the ovarian cell line is PA-1.

Claim 78: Cancel.

2. The following is an examiner's statement of reasons for allowance: the conserved sequence substitutions of SEQ ID No: 2 are unobvious variations over the prior art disclosure of SEQ ID No: 2, especially since the claimed substitutions are non-conserved amino acids. This makes the claimed invention novel and unobvious over the prior art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzanne M. Mayer, Ph.D. whose telephone number is 571-272-2924. The examiner can normally be reached on Monday to Friday, 8.30am to 5.00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Suzanne*  
SMM  
April 14, 2005

*[Signature]*  
ROBERT A. WAX  
PRIMARY EXAMINER  
Art Unit 1653